STATE OF MICHIGAN

DEPARTMENT OF LABOR & ECONOMIC GROWTH

OFFICE OF FINANCIAL AND INSURANCE SERVICES

Before the Commissioner of Financial and Insurance Services

In the matter of

XXXXX **File No. 84289-001**
Petitioner
v

Blue Cross Blue Shield of Michigan
Respondent
_____/

Issued and entered
this 27th day of November 2007
by Ken Ross
Acting Commissioner

ORDER

I
PROCEDURAL BACKGROUND

On August 6, 2007, XXXXX, authorized representative of XXXXX (Petitioner), filed a request for external review with the Commissioner of Financial and Insurance Services under the Patient's Right to Independent Review Act (PRIRA), MCL 550.1901 *et seq*. The Commissioner reviewed the material submitted and accepted the request on August 13, 2007.

Because the case involved medical issues, the Commissioner assigned it to an independent review organization (IRO) which provided its analysis and recommendations to the Commissioner on August 21, 2007.

II
FACTUAL BACKGROUND

The Petitioner receives health care benefits from Blue Cross Blue Shield of Michigan (BCBSM) under its *Community Blue Group Benefits Certificate* (Certificate). She was diagnosed with early stage breast cancer. As part of her care she was provided an Oncotype DX test, or assay to assist in determining the best course of treatment. The test, developed by Genomic Health, Inc. of San Francisco, evaluates genetic information from a tumor sample to generate a

result (a "Recurrence Score") which quantifies the likelihood of cancer recurrence. The test results can also be used to help determine whether hormone therapy alone will be sufficient or whether additional treatment through chemotherapy is needed. Genomic Health has patented the test and, at present, is the only laboratory performing the test.

The test was provided on January 20, 2006. The cost of the test was $3,460.00. BCBSM denied payment because it considers the test an experimental procedure. The Petitioner appealed. After a managerial-level conference on July 23, 2007, BCBSM did not change its decision and issued a final adverse determination on July 25, 2007.

III
ISSUE

Did BCBSM properly deny coverage for the Petitioner's Oncotype DX test?

IV
ANALYSIS

Petitioner's Argument

For this appeal, the Petitioner elected to be represented by Genomic Health which submitted written materials to the Office of Financial and Insurance Services (OFIS). The following are excerpts from Genomic Health's position paper:

> XXXXX has been diagnosed with early stage breast cancer and formally denied access to the Oncotype DX assay. This assay is clinically validated to assess the likelihood of distant recurrence in women with stage I or II, node negative, estrogen receptor positive breast cancer and provides valuable insight when making adjuvant therapy decisions.
>
> There is also evidence that the Recurrence Score can predict response to chemotherapy. A study looking at an additional group of patients on an NSABP protocol was published online (May 23, 2006) in the Journal of Clinical Oncology. . . . The. . . study of 651 patients demonstrated that breast cancer patients with high Recurrence Scores as identified by the Oncotype DX assay, also have a large absolute benefit from chemotherapy. This group represents about 25 percent of Patients with node negative, estrogen receptor positive breast cancer. Patients with low recurrence Scores derive minimal, if any, benefit from chemotherapy and represents about 50 percent of these patients. Gianni, et al., recently published an article showing, as well, that a high Recurrence Score was correlated with the likelihood of a pathologic complete response to chemotherapy for breast cancer patients in the neoadjuvant setting. . . . The [American Society of Clinical Oncology's] ASCO Foundation also recognizes Oncotype DX as an important tool

> available to physicians and patients when planning breast cancer treatment on their People Living with Cancer website: www.plwc.org
>
> Many payors have already put positive coverage policies in place for this important new test. Effective February 27, 2006, Oncotype DX is a covered service for Medicare beneficiaries. Coverage policies include a number of the "Blues" such as BS Federal, BCBS Alabama, BCBS Horizons New Jersey, Blue Shield California, BCBS South Carolina, BCBS Minnesota, Medical Mutual, Carefirst, and Highmark. In addition Kaiser Permanente, the OPM, Aultcare, Avmed, Dupage, FHHS, Group Health Cooperative, Harvard Pilgrim, United Mine Workers, UPMC, Humana, M-Care, Premera, Presbyterian Health Plan, Providence Health Plan, Sierra Health Plan, Tufts and most recently United Health Care, Aetna and Cigna also cover Oncotype DX to name just a few. To date, over 300 private payors have covered this test for individual patients for whom it was medically necessary, even where no formal coverage policy is in place.

The articles cited in the position paper quoted above are:

> Simon, R. Roadmap for developing and validating therapeutically relevant genomic classifiers. *Journal of Clinical Oncology*, October 10, 2005, vol. 23, no. 29.
>
> Paik, S., et al. A multigene assay to predict recurrence of tamoxifen-treated, node-negative breast cancer. *New England Journal of Medicine*, December 30, 2004. 351:2817-26.
>
> Habel, L., et al. A population-based study of tumor gene expression and risk of breast cancer death among lymph node-negative patients. *Breast Cancer Research* 2006, published online at http://breast-cancer-research.com/content/8/3/R25 5/31/06.
>
> Paik, S., et al. Expression of the 21 genes in the recurrence score assay and prediction of clinical benefit from tamoxifen in NSABP Study B-14 and chemotherapy in NSABP Study B-20. *Journal of Clinical Oncology*, May 23, 2006 (online edition).
>
> Gianni, L., et al. Gene expression profiles in paraffin-embedded core biopsy tissue predict response to chemotherapy in women with locally advanced breast cancer. *Journal of Clinical Oncology*, October 10, 2005, vol. 23, no. 29.

BCBSM's Argument

In its final adverse determination issued to Petitioner on July 25, 2007, BCBSM referenced its *Community Blue* certificate of coverage indicating that experimental treatment or services are not payable:

> As you were previously informed our medical staff reviewed the records and concluded that the laboratory procedure is considered experimental in nature. Therefore, we are unable to issue reimbursement and the charge remains your responsibility.

BCBSM did not offer any additional information in support of its decision. However, in its position paper of August 21, 2007 filed with OFIS for this appeal, BCBSM stated that "the effectiveness of the Oncotype gene test in the management of breast carcinoma had not convincingly been established." BCBSM stated that its medical consultant reviewed the medical documentation and determined that, at the time the Petitioner received this service, the Oncotype DX test was not a generally accepted standard for the diagnosis or management of her condition. BCBSM believes that this test is experimental and, therefore, not a covered benefit.

Commissioner's Review

This case is one of a series of recent PRIRA appeals of BCBSM decisions concerning the Oncotype DX test. Each of the Petitioners had the same diagnosis and were identical with respect to the nature of their disease as a qualifier for the Oncotype test. The issue to be resolved is whether the test is experimental. For each appeal, the medical records were presented by OFIS to an independent review organization (IRO) for analysis as required by section 11(6) of PRIRA (MCL 550.1911[6])

In the present case, the IRO physician reviewer framed the issue as "whether this test can improve the ability of clinicians to predict whether patients with node-negative, estrogen-receptor-positive (ER-positive) breast cancer should be treated with hormonal therapy or something else (such as chemotherapy)." According to the IRO reviewer, "[t]o date, no prospective trials have been published which show that this assay can improve the ability of physicians in treatment decisions over current methods. . . ." The IRO reviewer concluded that a lack of conclusive data meant that "this test is not considered medically necessary."

In other PRIRA appeals submitted to a different IRO, the IRO reviewers concluded that the test was not investigational. To date, four IRO reports have concluded that the test was experimental; four concluded the test was not experimental. These varying IRO opinions present a dilemma in attempting to provide a fair and consistent outcome in these appeals. Simply accepting

each IRO opinion would bring about the unacceptable result of different benefits for individuals with the same coverage and the same medical condition.

BCBSM itself has now agreed to provide coverage for Oncotype tests performed since January 2007. BCBSM has not indicated to OFIS its reasons for changing its position. However, it is noted that the Blue Cross Blue Shield Association's medical advisory panel concluded on June 28, 2007 that the Oncotype test met the Association's criteria for tests involving women with the type of breast cancer at issue here. (The Committee in May 2005 had concluded that the test did not meet its criteria.)

Under the PRIRA, the Commissioner is not required to accept the IRO's recommendation. When the Commissioner rejects an IRO recommendation, the Commissioner must cite "the principal reason or reasons why the commissioner did not follow the assigned independent review organization's recommendation." See MCL 550.1911(16)(b). In the present case, the Commissioner does not accept the IRO recommendation for the following reasons.

First, there have been no published studies of the Oncotype test which concluded that the test was not yielding the kind of results it was designed to produce. Earlier decisions of insurers not to cover the test appear to have been based on what the insurers felt was a lack of evidence, not actual evidence of test failure.

Second, an increasing number of insurers have decided to offer coverage for the test. Genomic Health's position paper has cited a number of studies published between 2004 and 2006 supporting the utility of the test. The paper also lists more than 25 benefit plans which have in recent years agreed to provide coverage for the test. In light of the increasing evidence in recent years of the test's value, BCBSM's decision to begin coverage in January 2007 appears, if not arbitrary, then at least entitled to no particular deference. These decisions, based on growing evidence of the usefulness of the test, also reflect the evidence that the test can produce economic benefits to the insurer. Chemotherapy is not required in all cases of this form of breast cancer but is widely administered because there has been no reliable way to determine whether, with a

specific patient, the chemotherapy is needed or not. The Oncotype assay fills the need for a test which could provide such information. A test which enables patients and doctors to decide not to proceed with chemotherapy can save the patient unnecessary treatment while also saving the insurer the cost of the chemotherapy. Presumably, BCBSM has reaped the benefit of lower cancer treatment costs in those instances where a member has been tested at her own expense and, based on the results, has elected to forego chemotherapy.

Third, as noted above, the Commissioner must strive to be consistent in adjudicating appeals under the PRIRA.

For these reasons, the Commissioner finds that the Oncotype DX test is a covered benefit for Petitioner.

V
ORDER

Respondent BCBSM's July 25, 2007, final adverse determination is reversed. BCBSM is required to provide, within sixty days, coverage for Petitioner's Oncotype DX test provided on January 20, 2006, subject to any applicable co-pays and deductibles. BCBSM shall, within seven days of providing coverage, submit to the Commissioner proof it has implemented the Commissioner's Order. To enforce this Order, the Petitioner must report any complaint regarding the implementation of this Order to the Office of Financial and Insurance Services, Health Plans Division, toll free 877-999-6442.

Under MCL 550.1915, any person aggrieved by this Order may seek judicial review no later than sixty days from the date of this Order in the circuit court for the county where the covered person resides or the circuit court of Ingham County. A copy of the petition for judicial review should be sent to the Commissioner of the Office of Financial and Insurance Services, Health Plans Division, Post Office Box 30220, Lansing, MI 48909-7720.